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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,903	11/15/2005	Takashi Hirao	1254-0298PUS1	7071

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EXAMINER	
BERTAGNA, ANGELA MARIE	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
11/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/556,903	HIRAO ET AL.	
	Examiner	**Art Unit**	
	Angela M. Bertagna	1637	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 November 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-8*.
   Claim(s) withdrawn from consideration: *9-28*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

Continuation of 5. Applicant's reply has overcome the following rejection(s): (1) the objection to claim 1 and (2) the rejection of claims 1-8 under 35 U.S.C. 112, second paragraph.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments filed on November 9, 2009 have been fully considered, but they were not persuasive with respect to all of the previously made rejections. In particular, Applicant's arguments filed on November 9, 2009, regarding the rejections of claims 1-8 made under 35 U.S.C. 103(a) have been fully considered, but they were not persuasive.

Regarding the rejection of claims 1-3, 6, and 8 under 35 U.S.C. 103(a) as being unpatentable over Hirao in view of Haugland, Applicant first argues that the combined teachings of Hirao and Haugland do not suggest all of the claimed limitations (see pages 11-14). In particular, Applicant initially states that the methods of Haugland are fundamentally different from those of Hirao, since the methods of Haugland are directed to PCR-based methods for detecting the amount of a specific fungus in an environmental sample, whereas the methods of Hirao are directed to detecting the amount of a particular plant genus in a food sample or food ingredient (see page 13). Applicant also argues that neither Hirao nor Haugland teaches or suggests the following limitations recited in independent claim 1: (i) determining the copy number of a DNA from a standard plant genus and the copy number of a DNA from a target (specific) plant genus in a sample for correction, (ii) determining the copy number of a DNA from a standard plant genus and the copy number of a DNA from a target (specific) plant genus in a test sample, and (iii) calculating the amount of the target (specific) plant genus present in the sample using the recited formula (see pages 13-14).

This argument was not persuasive, because as discussed previously, Haugland teaches a method that comprises adding a known amount of a standard fungal sample (Geotrichum candidum) to the sample to be tested and measuring the copy number of the standard fungal species and the copy number of the target fungal species by real-time PCR (see pages 330-332). Haugland further discloses that the method comprises preparation of a sample for correction (i.e. the calibrator) containing a known amount of the target fungal species (Stachybotrys chartarum) and a known amount of the standard fungal species (Geotrichum candidum) and determining the copy number of the target and standard fungal species by real-time PCR (pages 330-332). Haugland further teaches that the standard fungal species is added to the sample for correction and the test sample in the same amount (pages 330 and 332). Haugland teaches that "Ratios of target sequences determined in the test and calibrator samples were then multiplied by the known quantities of S. chartarum conidia in the calibrator samples to obtain estimates of the absolute quantities of these conidia in the test samples (page 332, column 2)." It is noted that conducting the above analysis as taught by Haugland results in the calculation step recited in the instant claim 1 with the exception of a conversion of the resulting amount to parts per million (ppm). It is also noted that the methods described by Haugland inherently provide a copy number determination, which is used in the ratio calculation described at page 332. Since Haugland further teaches that conducting the above analysis allows the experimenter to normalize the calculated amounts of a target nucleic acid for potential sample to sample variations in DNA extraction efficiency (see page 334, column 2), the ordinary artisan would have been motivated to utilize a sample for correction and perform the associated analysis as taught by Haugland and described above using a standard plant sample in order to obtain the ability to control for sample to sample variations in DNA extraction efficiency when practicing the methods of Hirao. An ordinary artisan also would have been motivated to express the resulting amount in any suitable units, such as the claimed parts per million, recognizing that the units were not critical and should be selected as a matter of design choice. Thus, the combined teachings of Hirao and Haugland result in all of the limitations recited in claims 1-3, 6, and 8.

Furthermore, in response to applicant's argument that the Haugland reference is nonanalogous art (see page 13), it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the teachings of Haugland are in the same field as Applicant's invention (i.e. methods for detecting the presence of a contaminant via PCR). Also, the teachings of Haugland are reasonably pertinent to the problem with which the Applicant was concerned, namely the use of calibrator samples to improve the accuracy and provide an additional control in methods of detecting contaminants in environmental samples via PCR amplification. Accordingly, the Haugland reference is not nonanalogous art.

Applicant also argues that Haugland teaches away from the claimed invention (see page 14). In particular, Applicant argues that Haugland teaches away from the claimed methods by stating that utilizing the correction factor from the calibrator sample did not improve the accuracy of the method (see page 14).

This argument was not persuasive, because as noted in MPEP 2123 and 2141.02, a teaching away in the prior art requires an active disparagement or discouragement of the proposed solution. Although Haugland teaches that the use of the calibrator sample did not improve the accuracy of the disclosed method, the reference also explicitly states that the use of calibrator samples may nevertheless be useful in other studies (page 330, column 2 and page 339, column 2). Specifically, Haugland states, "The comparative analysis of these sequences did not improve the accuracy of the method for quantifying S. chartarum conidia in this study but still may be a useful indicator of PCR inhibition (page 330, column 2)." Haugland also states, "The routine comparative analyses of externally supplied reference sequences in test and calibrator samples is therefore a prudent measure for ruling out the possibility of such interferences when performing analyses of environmental samples (page 339, column 2)." These teachings of Haugland would have indicated to the ordinary artisan practicing the method of Hirao that the use of calibrator samples as disclosed by Huagland would provide a useful means of eliminating the possibility of erroneous results stemming from the co-extraction of PCR inhibitors during the DNA purification step.

Since Applicant's arguments were not persuasive, the rejection of claims 1-3, 6, and 8 under 35 U.S.C. 103(a) as being unpatentable over Hirao in view of Huagland has been maintained.

Regarding the rejections of claims 4, 5, and 7 made under 35 U.S.C. 103(a) citing Hirao and Haugland as the primary combination of references, Applicant argues that the additional secondary references cited in these rejections do not overcome the deficiencies in the primary combination of references (see page 15). This argument was not persuasive, because as discussed above, the combined teachings of Hirao and Haugland render obvious the methods of claims 1-3, 6, and 8. Since Applicant's arguments were not persuasive, the rejections have been maintained.